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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/762,304 | 04/16/2001 | Franz Josef Meyer-Almes | P66378US0 | 4840 |

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EXAMINER

RAWLINGS, STEPHEN L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 07/02/2002

07

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,304

Applicant(s)

MEYER-ALMES, FRANZ JOSEF

Examiner

Stephen L. Rawlings, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Election facsimile cover sheet*.

DETAILED ACTION

1. The amendment filed April 16, 2001 in Paper No. 5 is acknowledged and has been entered. Claims 3-8 and 11 have been amended.
2. Claims 1-11 are pending in the application and are currently subject to restriction and an election requirement.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, drawn to a method for determining the chemosensitivity of cells.

Group II, claim(s) 9-11, drawn to a kit.

4. The inventions listed as groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of group I is determining the chemosensitivity of cells.

The special technical feature of group II is producing and using a kit.

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Accordingly, groups I and II are not linked by the same or corresponding special technical feature so as to form a single general inventive concept. PCT Rules 13.1 and 13.2 only provide for a single general inventive concept comprising the first claimed product, the first claimed method for producing said product, and the first claimed method for using said product; the method in I does not use the product in group II.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claim 1 is generic to a plurality of species wherein said cells are selected from the group consisting of (a) leukemia and reference cells, (b) solid tumor and reference cells, and (c) cells of pathological organs and reference cells.

Claim 1 is generic to a plurality of species wherein said substances are selected from the group consisting of (d) chemotherapeutic and pharmaceutical agents, (e) environmental pollutants, (f) peptides, (g) nucleic acid molecules and derivatives thereof, and (h) PNAs.

Claim 1 is generic to a plurality of species wherein said measuring of caspase activity is selected from the group consisting of (i) measuring caspase substrate turnover, (j) measuring binding of antibodies or derivatives thereof to caspase, (k) measuring binding of aptamers to caspase, (l) measuring binding of proteins to educts of caspase substrates, and (m) measuring binding of proteins to products of caspase substrates.

Claim 1 is generic to a plurality of species wherein said marker is selected from the group consisting of (n) a dye portion, (o) a colloidal precious metal, (p) a radioactive isotope, and (q) a rare-earth metal chelate.

6. Applicants are required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also

identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

7. Upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of species (a) is determining the chemosensitivity of leukemia and reference cells.

The special technical feature of species (b) is determining the chemosensitivity of solid tumor and reference cells.

The special technical feature of species (c) is determining the chemosensitivity of cells of pathological organs and reference cells.

The special technical feature of species (d) is determining the chemosensitivity of cells to a chemotherapeutic or pharmaceutical agent or agents.

The special technical feature of species (e) is determining the chemosensitivity of cells to an environmental pollutant or pollutants.

The special technical feature of species (f) is determining the chemosensitivity of cells to a peptide or peptides.

The special technical feature of species (g) is determining the chemosensitivity of cells to a nucleic acid molecule(s) and derivative(s) thereof.

The special technical feature of species (h) is determining the chemosensitivity of cells to a PNA or PNAs.

The special technical feature of species (i) is measuring caspase substrate turnover.

The special technical feature of species (j) is measuring binding of antibodies or derivatives thereof to caspase.

The special technical feature of species (k) is measuring binding of aptamers to caspase.

The special technical feature of species (l) is measuring binding of proteins to educts of caspase substrates.

The special technical feature of species (m) is measuring binding of proteins to products of caspase substrates.

The special technical feature of species (n) is measuring a dye portion.

The special technical feature of species (o) is measuring a colloidal precious metal.

The special technical feature of species (p) is measuring a radioactive isotope.

The special technical feature of species (q) is measuring a rare-earth metal chelate.

Accordingly, species (a)-(c), (d)-(h), (i)-(m), and (n)-(q) do not share the same or corresponding special technical feature so as to form a single general inventive concept.

9. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Stephen L. Rawlings, Ph.D.

Examiner

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slr

July 1, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600



RESTRICTION ELECTION FACSIMILE TRANSMISSION

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